BOB HOLDEN
GOVERNOR

MISSOURI
DEPARTMENT OF SOCIAL SERVICES
DIVISION OF MEDICAL SERVICES
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Dear Interested Party:

Effective July 1, 2002, the Missouri Medicaid Pharmacy Program began prior authorizing all new drug entities, and new drug product dosage forms of existing drug entities. These prior authorization restrictions will continue through the review process, committee recommendations are made, and the Division makes a final determination.

The Division of Medical Services (DMS) Clinical Pharmacist will conduct the reviews of the new drug products. The drugs for review are identified weekly from DMS First Data Bank price update reports, then immediately coded as "Prior Authorization required." For unrestricted drug status consideration for your product, a more detailed review request should be presented to DMS. These submissions should generally follow the AMCP guideline format. Enclosed are the abbreviated AMCP guidelines, which contain the Division's minimum requirements for submission.

If you have any questions concerning the new drug submission process, or the policy surrounding the prior authorization of all new drugs, feel free to contact Rhonda Driver, Clinical Pharmacist, at mailto:Rhonda.Driver@dss.mo.govor (573) 751-6961.

Sincerely,

George Oestreich
Director Pharmacy Program

GLO:mbm
Enclosure

MISSOURI MEDICAID NEW DRUG GUIDELINES

I. Product Description and Pricing Information (10 pages maximum)

- Generic, brand name, and therapeutic class of the product.
- All dosage forms, including strengths and package sizes.
- NDC (National Drug Code) for all formulations
- A copy of the official product labeling/literature.
- AWP cost per unit size.
- WAC cost per unit size.
- Federal Rebate percent.
- Supplemental Rebate percent.
- FDA approved (or other studied) indications. Include detailed discussion of the approved FDA indications and the date the approval was granted (or expected to be granted). Date for all off-label use, if available, should be included.
- Pharmacology
- Pharmacokinetics
- Contraindications
- Warnings/Precautions
- Adverse Effects
- Interactions, include:
    - Drug/Drug
    - Drug/Food
    - Drug/Disease
- Dosing and Administration

II. Supporting Clinical and Economic Information – Submit key clinical and economic studies that have been conducted, whether published or not, for clinical safety, efficacy, and economic evaluations. (10 pages maximum)

- Studies reported should be summarized in a clear, concise format; presenting data from multiple studies in tabular form within a category is strongly encouraged.
- Provide a summary of pivotal safety and efficacy trial for the product (maximum of five studies).
- Include any head-to-head comparison clinical studies between the proposed product and the principal competitors.

III. Product Impact – Submit the clinical condition being treated and the role of the product in its treatment to adequately assess the impact of the new product. Present a brief summary of information for the literature for each topic. (15 pages maximum)

- Epidemiology and relevant risk factors.
- Pathophysiology
- Clinical Presentation
- Approaches to treatment
    - Principal Options
    - Practice Patterns
- Description of alternative treatment options (both drug and non-drug)
- Place of the proposed therapy in treatment (e.g. first line)
- Expected outcomes of therapy

- Summarize any studies or reports to evaluate the impact of the product as part of a disease or case management intervention strategy. (1 page maximum per study)

IV. Impact Model Report – Pharmacoeconomic model that combines estimates of the treatment effectiveness, the resources consumed (cost), and the system-wide effect the product will generate. Each model should incorporate comprehensive disease-based analytical information, even though specific formats may vary.

- A Clinical Pathway is the process of treatment utilizing a specific product or other intervention. Alternative Clinical Pathways presented will also be considered.
- Provide the number and characteristics of patients being treated by each Clinical Pathway.
- Include product and other medical resources necessary to support, as well as the costs consumed with each Clinical Pathway.
- Outcomes of therapy for each Clinical Pathway, including expected proportion of treatment failures, if known. These outcomes can be broadly defined and modeled from other data sources.
- When a product is to be used in the treatment of more than one disease, its impact should be modeled in each therapeutic area.
- This area allows the opportunity to communicate the value of the product in the health care community.

V. Safety and Efficacy – The primary considerations for accepting a new product are the safety and effectiveness of the product for the eligible population. Efficacy, as determined by clinical trial results, must be translated into effectiveness. (10 pages maximum)

- Manufacturers should provide their best estimate of the expected effectiveness outcomes in customary practice settings.
- Compliance, dosing, co-morbid conditions and the population of interest (e.g., elderly, children) should be taken into consideration.
    - ➤ It is recommended that documentation be provided indicating anticipated compliance patterns from populations similar to the eligible treatment population if available.